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10/553,671	10/17/2005	Valerie Bicard-Benhamou	MERCK-2686-2	1527

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EXAMINER
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ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
07/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,671	BICARD-BENHAMOU ET AL.	
	Examiner	Art Unit	
	NELSON C. BLAKELY III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19-37,42 and 43* is/are pending in the application.

4a) Of the above claim(s) *29-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17, 19-28, 33-37, 42 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

Claims 1-17, 19-37, 42 and 43 of the instant application are pending. Claims 29-32 are withdrawn pursuant to Applicant's Response, filed 05/13/2009. Accordingly, instant claims 1-17, 19-28, 33-37, 42 and 43 are presented for examination on their merits.

Applicant's request for reconsideration of the finality of the rejection of the last Office Action is persuasive and, therefore, the finality of that Action is ***withdrawn***.

Applicant's Arguments, filed 05/13/2009, have been fully considered. Rejections not reiterated from previous Office Actions are hereby ***withdrawn***. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Terminal Disclaimer

The terminal disclaimer, filed on 05/13/2009, disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of any patent granted on Application No. 10/553,668, has been reviewed and is accepted. The terminal disclaimer has been recorded.

Applicant's Amendment

Applicant's Amendment, filed 05/13/2009, wherein the specification and claims 1-17, 19-28, 32-37, 42 and 43 are amended, and claims 18, 38-41 and 44 are canceled, is acknowledged.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally ***limited to a single paragraph on a separate sheet*** within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Response to Arguments

Applicant's arguments, with respect to claims 1-17, 19-28, 33-37, 42 and 43, previously rejected under 35 U.S.C. 103(a), have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-17, 19, 33-37, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Senga *et al*. (U.S. Patent No. 6,489,018B2), in view of Bagala, Sr. (U.S. Patent No. 7,045,007B2; Cited in a previous Action), as evidenced by Seo *et al*. (Cosmetics and Toiletries®, Vol. 112, pages 83-90; 1997; Cited by Applicant) and Rick *et al*. (U.S. Patent Application Publication No. 2004/0177788A1).

With regard to instant claims 1-3, 6-17, 19, 33-37, 42 and 43, Senga *et al*. disclose, in column 6, lines 26-59, metallic luster pigments based on synthetic mica (instant claims 7-9) as a core material having a lower impurity content and a lower content of iron and other metal ions, which are a coloring factor (e.g., dopant; instant claim 13), as compared with the metallic luster pigments bases on natural mica. Further, in the instant excerpt, Senga *et al*. disclose that pigments based on synthetic

mica have excellent transparency and are highly lustrous and glittering. Even further, in the instant excerpt, Senga *et al*. disclose effective examples of said pigments include pigments which are obtained by coating the surface of a synthetic mica with one or more metal oxides comprising titanium (instant claims 14 and 15), as the main component, and iron, comprising a metallic luster of silver, wherein the shape of the mica includes flat shapes, i.e., platelet-shaped (instant claim 6).

Senga *et al*. fail to disclose specifically wherein the pigment comprises silver oxide and is obtainable by agitating at 10-60 ˚C, and wherein the amount of silver oxide is in the range of 0.01 to 0.5% by weight, based on the total weight of the inorganic pigment (instant claim 1). However, Bagala, Sr. *et al*. disclose, in reference claims 1-8, columns 11 and 12, an effect pigment comprising metal oxide-coated laminar platelets in which the platelets are a mixture of about 5 to 90% platy glass and 90 to 5% platy mica, i.e., synthetic mica (reference column 1, line 50), wherein the metal oxide comprises iron oxide (inorganic colorant or dopant; instant claim 13) and titanium dioxide. In the instant excerpt, Bagala, Sr. *et al*. further disclose wherein the metal oxide coating comprises a plurality of layers, each of which comprises a metal oxide. In column 4, lines 38-52, Bagala, Sr. *et al*. disclose effect pigments constructed with a reflecting layer, i.e., silver, which is overcoated with a low index of refraction material typically having a refractive index from 1.3 to 2.5, which, in turn, may be overcoated with a layer comprising iron and titanium dioxides. Bagala, Sr. *et al*., disclose, in column 6, lines 52-63, applications in which the referenced pigments may be used, such as mascara cake/cream, shaving cream and eye shadow cream (instant claim 3).

Additionally, in Example 45, Bagala, Sr. *et al*. disclose a 100 g mixture of glass flakes and mica stirred, or agitated, at room temperature. In the instant excerpt, Bagala, Sr. *et al*. further disclose wherein 7.87 grams [7.87 g/50 g (half of original mixture) = 0.1574% silver based on the inorganic pigment; instant claim 1] of silver nitrate crystals were added to the slurry, and the mixture was dried at 100 ˚C. Subsequently, tetraethoxysilane (silica source) is added to the slurry and stirred, at room temperature for 7 hours (instant claim 35), and the silica-coated product (instant claims 16 and 17) is washed and oven dried.

Bagala, Sr. *et al*. fail to disclose specifically wherein the antimicrobial pigment is obtainable by agitating at 10-60 ˚C, comprises silver oxide (instant claims 1 and 34), wherein the pigment particles with silver oxide are prepared by agitating the suspension from 8 to 20 hours (instant claims 36 and 37), or wherein the amount of the pigment particles in the formulation is 0.1-70% by weight, based on the total weight of the formulation (instant claim 43). However, it is not inventive to discover the optimum ranges or regimens by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) and MPEP §2144.05(II). In addition, Applicant recites on page 12, line 27, through page 13, line 7, wherein similar pigments with antimicrobial activity can be obtained by substituting silver oxide by other antimicrobial compounds, such as silver nitrate. Additionally, Applicant recites on page 14, line 14-20, a further embodiment of a method for producing pigments wherein the pigments are further coated with a protective coating layer comprising silica, which is added to the agitated suspension and

heated to a temperature between 60 and 90 ˚C. Therefore, the determination of the optimum characterization of the composition and temperatures, as disclosed by Bagala, Sr. *et al*., would have been a matter well within the purview of one of ordinary skill in the art, at the time of the invention, through no more than routine experimentation.

Furthermore, as recited in MPEP 2113, product-by-process claims are not limited to the manipulations of the recited steps, i.e., obtainable by agitating at 10-60 ˚C, only the structure. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claims is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964 (Fed. Cir. 1985).

Senga *et al*. fail to disclose specifically wherein the formulation additionally comprises preservatives and antimicrobial agents (instant claim 19), or wherein the formulation further comprises at least one customary excipient, e.g., wax, (instant claim 33). However, Seo *et al*. disclose, on page 83, first column, lines 1-10, wherein cosmetics consist of, for example, hydrocarbons (e.g., oils and waxes), and may easily be contaminated and/or utilized as nutrients by microorganisms, and subsequently, organic preservatives should be used in cosmetic formulas. Further, Seo *et al*. disclose on page 83, second column, lines 3-9, metals and their compounds showing antimicrobial activity, such as silver.

Senga *et al*. fail to disclose specifically wherein the undesirable side-effects caused by microorganisms are dandruffs, acne and/or malodor (instant claim 2); however, an intended use of the formulation, wherein the physical, structural, and functional components are identical or substantially similar, is not sufficient to patentably distinguish the claimed medicament over the prior art product containing identical physical and structural components [MPEP 2111.02 (II)].

Senga *et al*. fail to disclose specifically wherein the one or more layers of transparent, semitransparent or opaque, selectively absorbing, nonselectively absorbing or nonabsorbing metal oxides, i.e., TiO_2, are arranged as alternating layers with the refractive index $n > 1.8$ and $n \leq 1.8$ (instant claims 10-12), or wherein the maximum deviation for the L value is $-6 \leq \Delta L \leq 6$, and a and b are both $-5 \leq \Delta a/\Delta b \leq 5$ (instant claims 1 and 42). However, it is not inventive to discover the optimum ranges or regimens by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) and MPEP §2144.05(II). In addition, Rick *et al*. disclose, in reference claims 1-4, 9-11 and 13-15, page 8, an interference pigment, comprising a flake-form substrate, i.e., synthetic mica, with successive coatings of a colorless coating having a refractive index of $n > 1.8$, a refractive index of $n \leq 1.8$ and an outer protective layer, comprising, for example, titanium dioxide (TiO_2), iron oxide (Fe_2O_3 or Fe_3O_4; dopant) and silver oxide (Ag_2O). Furthermore, in Examples 1-4, pages 4 and 5, Rick *et al*. contemplate the values of L, a and b. Therefore, the determination of the optimum characterization of the composition would have been a matter well within the purview of one of ordinary

skill in the art, at the time of the invention, through no more than routine experimentation.

Thus, a skilled artisan would have envisaged the instantly claimed antimicrobial pigment, as disclosed by Senga *et al*. and Bagala, Sr. *et al*., and evidenced by Seo *et al*. and Rick *et al*. One of ordinary skill in the art would have been motivated to combine the teachings of the aforementioned references when preparing an antimicrobial pigment with low impurity content, excellent transparency and one that is visually homogeneous, despite the differences in thickness and refractive index of the platelet layers. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are fairly suggestive of the claimed invention.

Accordingly, the instant invention, as claimed in claims 1-3, 6-17, 19, 33-37, 42 and 43, is *prima facie* obvious over the combination of the aforementioned teachings.

Claims 4, 5, 20-28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Senga *et al*. (U.S. Patent No. 6,489,018B2), in view of Bagala, Sr. (U.S. Patent No. 7,045,007B2; Cited in a previous Action), as evidenced by Seo *et al*. (Cosmetics and Toiletries®, Vol. 112, pages 83-90; 1997; Cited by Applicant) and Rick *et al*. (U.S. Patent Application Publication No. 2004/0177788A1), as applied to claims 1-3, 6-17, 19, 33-37, 42 and 43 above, and further in view of Vollhardt (U.S. Patent No. 6,274,124B1; Cited in a previous Action) and Scott *et al*. (U.S. Patent No. 6,482,397B1; Cited in a previous Action), as evidenced by Hashim (Oil Palm Bulletin, Vol. 47, pages

37-48; 2003; Cited in a previous Action) and De Tommaso (International Publication No. WO02/04012A1; Cited in a previous Action).

The teachings of Senga *et al*. are recited *supra*.

With regard to instant claims 4, 5, 20-28 and 33, Senga *et al*. fail to disclose specifically wherein a protein is a suitable substrate for microorganisms (instant claims 4 and 5), or wherein antioxidants (instant claim 25) and customary excipients, such as waxes and paraffins (instant claim 33), are included in the formulation. However, in the Abstract and Table 1, page 37, Hashim discloses, for evidentiary purposes, that cosmetic products contain variable amounts of nutrients that support microbial growth. In the instant excerpt, Hashim further discloses conventional raw materials used in cosmetic products, such as waxes, paraffins, protein, color and pigments, preservatives and antioxidants.

Senga *et al*. fail to disclose specifically the inclusion of ingredients, such as one or more UV filters, skin-protecting or skin-care active ingredients, or at least one photostabilizer (instant claims 22, 27 and 28, respectively). However, Vollhardt discloses, in the Abstract, a conventional cosmetic or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin of humans. Vollhardt discloses, in column 4, line 36 through column 5, line 54, wherein the formulation is suitable for the addition of 1,2-pentanediol, an emulsifier, which in addition to UV filter substances, may comprise antioxidants and inorganic pigments. Furthermore, in the instant excerpt, Vollhardt discloses wherein the

formulation may further comprise at least one antiperspirant and/or at least one skin whitening compound, which would have been reasonably construed by a skilled artisan, at the time of the invention, to be skin-protecting or skin-care active ingredients. In column 1, lines 42-49, Vollhardt discloses the UV filter substance 2-phenylbenzimidazol, a known photostabilizer. Additionally, in column 2, lines 12-20, Vollhardt discloses wherein the aforementioned inorganic pigments, coated or uncoated, are known to be used in sunscreen products to help protect the skin from UV rays. In the instant excerpt, Vollhardt further discloses wherein the inorganic pigments, such as oxides of titanium, zinc and iron, are typically used in addition to organic UV filter substances. Therefore, a skilled artisan would have envisaged the modified antimicrobial cosmetic pigment of the combined teachings, as disclosed by Senga *et al*. and Bagala, Sr., further comprising conventional active ingredients, such as UV filter substances, skin-protecting or skin-care active ingredients, and at least one photostabilizer, as disclosed by Vollhardt. One of ordinary skill in the art would have been motivated to combine the teachings of the aforementioned references when seeking a novel cosmetic or dermatological composition with increased water resistance and light (sun) protection. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are fairly suggestive of the claimed invention.

Senga *et al*. and Vollhardt fail to disclose specifically the inclusion of ingredients, such as at least one antibiotic (vancomycin; instant claims 20 and 21), at least one self-tanning agent (instant claim 23) and vitamins (instant claim 26); however, Scott *et al*.

disclose, in reference claims 1-3, a composition comprising an artificial tanning effective amount of a self-tanning agent, i.e. dihydroxyacetone (DHA), a coloring agent, and a cosmetically acceptable carrier adapted for topical application to human skin. Additionally, Scott *et al*. disclose, in column 1, lines 52-65, that though DHA is used as a widely accepted self-tanning agent, coloring agents are included in sunless tanning compositions to provide the applier the ability to more accurately assess where they have applied the compositions to their skin. In column 4, line 49, through column 5, line 42, Scott *et al*. disclose wherein the composition further comprises antimicrobial agents, or antibiotics, preservatives, antioxidants, vitamins and waxes, for example. In the instant excerpt, Scott *et al*. further disclose wherein antimicrobial agents and preservatives inhibit microbial growth in the compositions, and can be used to treat infected, or potentially infected, areas of skin.

Senga *et al*. and Scott *et al*. fail to disclose specifically wherein the antibiotic is vancomycin; however, De Tommaso discloses, on page 1, lines1-7, an anhydrous pharmaceutical composition comprising vancomycin, a glyocpeptide antibiotic having a broad spectrum of antimicrobial activity, for topical use.

Therefore, a skilled artisan would have envisaged the modified antimicrobial cosmetic pigment of the combined teachings, as disclosed by Senga *et al*., Bagala, Sr. and Vollhardt, further comprising conventional active ingredients, such as at least one antibiotic, i.e., vancomycin, at least one self-tanning agent, i.e., dihydroxyacetone, and vitamins, as disclosed by Scott *et al*., and evidenced by De Tommaso. One of ordinary skill in the art would have been motivated to combine the teachings of the

aforementioned references when preparing a composition comprising a light, water and heat resistant antimicrobial inorganic pigment to be applied topically, wherein the included coloring agent aides in assuring even application of said composition. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are fairly suggestive of the claimed invention.

Accordingly, the instant invention, as claimed in claims 4, 5, 20-28 and 33, is *prima facie* obvious over the combination of the aforementioned teachings.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NELSON C. BLAKELY III whose telephone number is (571) 270-3290. The examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614
July 1, 2009

/N. C. B. III/

Examiner, Art Unit 1614